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(54) BLOOD SAMPLE MANAGEMENT USING OPEN CELL FOAM

BLUTPROBENVERWALTUNG MIT OFFENZELLIGEM SCHAUMMATERIAL

GESTION D'ÉCHANTILLON DE SANG AU MOYEN DE MOUSSE A CELLULES OUVERTES

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Description

BACKGROUND OF THE INVENTION

1. Field of the Disclosure

[0001] The present disclosure relates generally to a blood transfer device. More particularly, the present disclosure relates to a blood transfer device, a blood transfer and testing system, a lancet and blood transfer device, and a method of loading an anticoagulant.

2. Description of the Related Art

[0002] Blood sampling is a common health care procedure involving the withdrawal of at least a drop of blood from a patient. Blood samples are commonly taken from hospitalized, homecare, and emergency room patients either by finger stick, heel stick, or venipuncture. Once collected, blood samples may be analyzed to obtain medically useful information including, for example, chemical composition, hematology, and coagulation.

[0003] Blood tests determine the physiological and biochemical states of the patient, such as disease, mineral content, drug effectiveness, and organ function. Blood tests may be performed in a clinical laboratory or at the point-of-care near the patient. US 2002/164825 A1 discloses a cell filtration system comprising a filter housing having an inlet for the introduction of blood to be filtered, as well as an outlet for the removal of filtered blood. Additionally, a filter element is disposed within the housing, with the filter element comprising a plurality of beads configured to promote the adhesion of, e. g. cancer cells.
In addition, EP 0 219 053 A2 discloses a blood filtration device with a collapsible venous blood reservoir with a heparin-coated filter element.
Furthermore, WO 2011/077757 A1 discloses a storage device for liquid to be tested, with a collection means which holds a filter for absorbing the liquid to be tested, a pressing means which presses an upper end side of the filter held by the collection means and pushes the filter downward out of the collection means, and a containing means which contains in a storing liquid the filter pushed out by the pressing means.
WO 2009/155612 A2 discloses a device for collecting, shipping and storing biological samples in a dry state. The disclosed device comprises an enclosed housing with a first portion threadably engageable to a second portion.
Moreover, US 2009/107903 A1 discloses a dipstick coated with an anticoagulant that is selectively received by a rotor of a blood centrifuge.

SUMMARY OF THE INVENTION

[0004] According to the present invention, a specimen mixing and transfer device as defined in independent claim 1 is provided. Further preferred embodiments of the present invention are defined in the depending claims. The present disclosure provides a specimen mixing and transfer device adapted to receive a sample. The specimen mixing and transfer device includes a housing, a material including pores that is disposed within the housing, and a dry anticoagulant powder within the pores of the material. In one embodiment, the material is a sponge material. In other embodiments, the material is an open cell foam. In one embodiment, the open cell foam is treated with an anticoagulant to form a dry anticoagulant powder finely distributed throughout the pores of the material. A blood sample may be received within the specimen mixing and transfer device. The blood sample is exposed to and mixes with the anticoagulant powder while passing through the material.

[0005] A specimen mixing and transfer device of the present disclosure offers uniform and passive blood mixing with an anticoagulant under flow-through conditions. A specimen mixing and transfer device of the present disclosure could catch blood clots or other contaminants within the microstructure of the material and prevent them from being dispensed into a diagnostic sample port. A specimen mixing and transfer device of the present disclosure enables a simple, low-cost design for passive flow-through blood stabilization. A specimen mixing and transfer device of the present disclosure enables precisely controlled loading of an anticoagulant into the material by soaking it with an anticoagulant and water solution and then drying the material to form a finely distributed dry anticoagulant powder throughout the pores of the material.

[0006] A specimen mixing and transfer device of the present disclosure may provide an effective passive blood mixing solution for applications wherein blood flows through a line. Such a specimen mixing and transfer device is useful for small blood volumes, e.g., less than 50 μL or less than 500 μL, and/or where inertial, e.g., gravity based, forces are ineffective for bulk manual mixing by flipping back and forth a blood collection container such as is required for vacuum tubes.

[0007] In accordance with an embodiment of the present invention, a specimen mixing and transfer device adapted to receive a sample includes a housing having a first end, a second end, and a sidewall extending therebetween; a material including pores and disposed within the housing; and a dry anticoagulant powder within the pores of the material.

[0008] In one configuration, the sample is a blood sample. In another configuration, the housing is adapted to receive the blood sample therein via the first end. In yet another configuration, with the blood sample received within the housing, the blood sample passes through the material thereby effectively mixing the blood sample with the dry anticoagulant powder. In one configuration, the blood sample dissolves and mixes with the dry anticoagulant powder while passing through the material. In another configuration, the material is an open cell foam. In yet another configuration, the material is a sponge. The first end includes an inlet. The second end includes an outlet. In yet another configuration, the housing defines a mixing chamber having a material including pores disposed within the mixing chamber. In one configuration, the housing includes an inlet channel in fluid communication with the inlet and the mixing chamber and an outlet channel in fluid communication with the mixing chamber and the outlet. In another configuration, the housing includes a dispensing chamber between the mixing chamber and the outlet.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] The above-mentioned and other features and advantages of this disclosure, and the manner of attaining them, will become more apparent and the disclosure itself will be better understood by reference to the following descriptions of embodiments of the disclosure taken in conjunction with the accompanying drawings, wherein:

Fig. 1 is a partial cross-sectional view of a specimen mixing and transfer device in accordance with an embodiment of the present invention.

Fig. 2 is a microscopic view of the microstructure of an open cell foam material having a dry anticoagulant powder distributed throughout its microstructure in accordance with an embodiment of the present invention.

Fig. 3 is a partial cross-sectional view of a specimen mixing and transfer device in accordance with another embodiment of the present invention.

Fig. 4 is a perspective view of a specimen mixing and transfer device which is not part of the present invention.

Fig. 5 is a partial cross-sectional view of a specimen mixing and transfer device which is not part of the present invention.

Fig. 6 is a partial cross-sectional view taken along line **6-6** of **Fig. 5** which is not part of the present invention.

Fig. 7 is a perspective view of a specimen mixing and transfer device which is not part of the present invention.

Fig. 8 is a partial cross-sectional view of a specimen mixing and transfer device which is not part of the present invention.

Fig. 9 is a partial cross-sectional view taken along line **9-9** of **Fig. 8** which is not part of the present invention.

Fig. 10 is a perspective view of alternate embodiments of a specimen mixing and transfer device which is not part of the present invention.

Fig. 11A is a perspective view of a syringe assembly in accordance with an embodiment of the present invention.

Fig. 11B is a close-up partial perspective view of the syringe assembly of **Fig. 11A** in accordance with an embodiment of the present invention.

Fig. 11C is a perspective view of a syringe assembly in accordance with an embodiment of the present invention.

Fig. 12 is a perspective view of an open cell foam material in accordance with an embodiment of the present invention.

Fig. 13 is a microscopic view of the microstructure of an open cell foam material having a dry anticoagulant powder distributed throughout its microstructure in accordance with an embodiment of the present invention.

Fig. 14 is a microscopic view of the microstructure of an untreated foam material.

Fig. 15 is a perspective view of a syringe assembly in accordance with an embodiment of the present invention.

Fig. 16 is a graph demonstrating the anticoagulant uptake by a blood sample flowing through an open cell foam material having a dry anticoagulant powder distributed throughout its microstructure in accordance with an embodiment of the present invention.

Fig. 17 is a perspective view of a blood transfer system in accordance with an embodiment of the present invention.

Fig. 18 is a perspective view of a blood transfer system in accordance with an embodiment of the present invention.

Fig. 19 is a perspective view of a blood transfer system in accordance with an embodiment of the present invention.

Fig. 20 is a perspective view of a blood transfer system in accordance with an embodiment of the present invention.

[0010] Corresponding reference characters indicate corresponding parts throughout the several views. The exemplifications set out herein illustrate exemplary embodiments of the disclosure.

DETAILED DESCRIPTION

[0011] The following description is provided to enable those skilled in the art to make and use the described embodiments contemplated for carrying out the invention.

[0012] For purposes of the description hereinafter, the terms "upper", "lower", "right", "left", "vertical", "horizontal", "top", "bottom", "lateral", "longitudinal", and derivatives thereof shall relate to the invention as it is oriented in the drawing figures. However, it is to be understood that the invention may assume various alternative variations, except where expressly specified to the contrary. It is also to be understood that the specific devices illustrated in the attached drawings, and described in the following specification, are simply exemplary embodiments of the invention. Hence, specific dimensions and other physical characteristics related to the embodiments disclosed herein are not to be considered as limiting.

[0013] **Figs. 1-3** illustrate exemplary embodiments of a specimen mixing and transfer device of the present disclosure. The specimen mixing and transfer device **10** is adapted to receive a sample **12.** In one embodiment, the specimen mixing and transfer device **10** includes a housing **14,** a material **16** including pores **18** that is disposed within the housing **14,** and a dry anticoagulant powder **20** within the pores **18** of the material **16.**

[0014] With a sample **12** received within the specimen mixing and transfer device **10,** a portion of the specimen mixing and transfer device **10** acts as a flow-through chamber for the effective mixing of a sample **12** with the dry anticoagulant powder **20** within the material **16.** In other embodiments, the material **16** may contain other dry substances. The effective mixing is achieved by passing the sample **12** through the material **16** having the dry anticoagulant powder **20** distributed throughout its microstructure.

[0015] A specimen mixing and transfer device **10** of the present disclosure offers uniform and passive blood mixing with an anticoagulant under flow-through conditions. A specimen mixing and transfer device **10** of the present disclosure may catch blood clots or other contaminants within the microstructure of the material **16** and prevent them from being dispensed into a diagnostic sample port. A specimen mixing and transfer device **10** of the present disclosure enables a simple, low cost design for passive flow-through blood stabilization. A specimen mixing and transfer device **10** of the present disclosure enables precisely controlled loading of an anticoagulant into the material **16** by soaking it with an anticoagulant and water solution and then drying the material **16** to form a finely distributed dry anticoagulant powder **20** throughout the pores **18** of the material **16.**

[0016] A specimen mixing and transfer device **10** of the present disclosure may provide an effective passive blood mixing solution for applications wherein blood flows through a line. Such a specimen mixing and transfer device **10** is useful for small blood volumes, e.g., less than 50 μL or less than 500 μL, and/or where inertial, e.g., gravity based, forces are ineffective for bulk manual mixing by flipping back and forth a blood collection container such as is required for vacuum tubes.

[0017] **Fig. 1** illustrates an exemplary embodiment of a specimen mixing and transfer device 10 of the present disclosure. Referring to **Fig. 1,** in one embodiment, a specimen mixing and transfer device **10** includes a housing **14,** a material **16** including pores **18** that are disposed within the housing **14,** and a dry anticoagulant powder **20** within the pores **18** of the material **16.** The housing **14** includes a first end **22,** a second end **24,** and a sidewall **26** extending between the first end **22** and the second end **24.** In one embodiment, the first end **22** includes an inlet **28** and the second end **24** includes an outlet **30.**

[0018] Referring to **Fig. 1,** in one embodiment, the housing **14** of the specimen mixing and transfer device **10** includes an inlet channel **32** and an outlet channel **34.** The inlet channel **32** and the outlet channel **34** are in fluid communication via a flow channel or mixing chamber **36.** For example, the inlet channel **32** is in fluid communication with the inlet **28** and the mixing chamber **36;** and the outlet channel **34** is in fluid communication with the mixing chamber **36** and the outlet **30.** In one embodiment, the material **16** is disposed within the mixing chamber **36** of the housing **14.**

[0019] In one embodiment, the material **16** is a sponge material. In other embodiments, the material **16** is an open cell foam. In one embodiment, the open cell foam is treated with an anticoagulant, as described in detail below, to form a dry anticoagulant powder **20** finely distributed throughout the pores **18** of the material **16.** A sample **12** may be received within the specimen mixing and transfer device **10.** In some embodiments, the sample **12** gets soaked into the material **16** based on capillary principles. In some embodiments, the sample **12** may be a blood sample. The blood sample is exposed to and mixes with the anticoagulant powder **20** while passing through the intricate microstructure of the material **16.** In this manner, the specimen mixing and transfer device **10** produces a stabilized sample. In some embodiments, the stabilized sample may be transferred to a diagnostic instrument such as a blood testing device, a point-of-care testing device, or similar analytical device.

[0020] In one embodiment, the material **16** is an open cell foam. For example, the material **16** is a soft deformable open cell foam that is inert to blood. In one embodiment, the open cell foam may be a melamine foam, such as Basotect® foam commercially available from BASF. In another embodiment, the open cell foam may consist of a formaldehyde-melamine-sodium bisulfite copolymer. The open cell foam may be a flexible, hydrophilic open cell foam that is resistant to heat and many organic solvents. In one embodiment, the open cell foam may be a sponge material.

[0021] A method of loading an anticoagulant to a material **16** having pores **18** will now be discussed. In one embodiment, the method includes soaking the material **16** in a liquid solution of the anticoagulant and water; evaporating the water of the liquid solution; and forming a dry anticoagulant powder **20** within the pores **18** of the material **16.**

[0022] The method of the present disclosure enables precisely controlled loading of an anticoagulant into the material **16** by soaking it with an anticoagulant and water solution and then drying the material **16** to form a finely distributed dry anticoagulant powder **20** throughout the pores **18** of the material **16,** as shown in **Fig. 2.**

[0023] Anticoagulants such as Heparin or EDTA (Ethylene Diamine Tetra Acetic Acid), as well as other blood stabilization agents, could be introduced into the material **16** as a liquid solution by soaking the material **16** in the liquid solution of a desired concentration. After evaporating the liquid phase, e.g., evaporating the water from a water and Heparin solution, a dry anticoagulant powder **20** is formed and finely distributed throughout the internal structure of the material **16,** as shown in **Fig. 2.** For example, the dry anticoagulant powder **20** is formed and finely distributed throughout the pores **18** of the material **16.** In a similar manner, the material **16** could be treated to provide a hydrophobic, hydrophilic, or reactive internal pore surface.

[0024] In one configuration, a key advantage of providing an open cell foam as the material **16** is that a known amount of anticoagulant may be loaded into the pores **18** of the foam material. A desired concentration of an anticoagulant may be dissolved in water or other suitable solvent and then introduced into the pores **18** of the open cell foam material **16** in liquid form. In one embodiment, the anticoagulant may be loaded into the pores **18** by dipping the open cell foam material **16** into a solution of anticoagulant and water or solvent and subsequently allowing the open cell foam material **16** to dry. The open cell foam material **16** may be allowed to dry in ambient air or in a heated oven. After drying, the anticoagulant may be distributed throughout the internal microstructure of the open cell foam material **16** in the form of a dry powder.

[0025] It is noted that suitable hydrophilic foam material having interconnected cell pores may be loaded with anticoagulant, as described above, and used as described herein for flow-through blood stabilization.

[0026] One key advantage of using a melamine-based open cell foam material is that melamine foams have a generally low analyte bias. As discussed herein, analyte bias is the difference in a measured value of an analyte as compared to a blood control value. Generally, analyte bias occurs when analytes adhere to a surface of a material, when analytes are leached from a material, via introduction of other components which may interfere with a measurement, or upon activation of a biological process. Additional open cell foam materials which are suitable for use as described herein include organic thermoplastic and thermosetting polymers and co-polymers, including but not limited to polyolefins, polyimides, polyamides, such as polyethylene terephthalate (PET), polypropylene (PP), polyethylene (PE), and the like. The material may be in fibrous structure, such as woven or random fiber form, or irregular 3D structure.

[0027] In order to avoid or minimize potential analyte bias associated with the housing **14** of the transfer device **10,** the material of the housing **14** may be treated. In one embodiment, the housing **14** may be treated with an additive coating which acts to block analytes from sticking to a surface. Additive coatings may include, but are not limited to, 1.) proteins, such as bovine serum albumin (BSA), casein, or non-fat milk, 2.) surfactants such as polysorbate 20 (Tween 20) and organosilicone (L-720), 3.) polymers and copolymers such as polyethylene glycol (PEG), polyvinyl alcohol (PVA), and polyvinylpyrrolidone (PVP), 4.) carbohydrates such as destran and glycosamino glycans, such as heparin, and 5.) cell membrane mimicking polymers such as Lipidure.

[0028] Alternatively, the housing **14** may be treated with a chemical surface modification. Chemical surface modifications can include, but are not limited to, 1.) gas plasma treatment, 2.) chemical bonding or polyethylene glycol (PEG) or other polymers to achieve a desired hydrophobicity or hydrophilicity, 3.) chemical modification of the surface to include hydrophilic compositions such as ethylene glycol, or hydrophobic groups, such as long carbon chains, and 4.) vapor deposition of a substance, such as parylene. It is appreciated herein that combinations of any of the above materials may be used to achieve the desired properties to minimize analyte bias for a specific analyte or group of analytes.

[0029] In one embodiment, the mixing chamber **36** includes the material **16** having a dry anticoagulant powder **20** therein. For example, referring to **Figs. 1 and 3,** the material **16** is disposed within the mixing chamber **36** of the specimen mixing and transfer device **10.** The anticoagulant can be loaded into the material **16** having pores **18** as described above.

[0030] Referring to **Fig. 1,** the housing **14** of the specimen mixing and transfer device **10** is adapted to receive a sample **12** therein via the first end **22.** For example, the housing **14** of the specimen mixing and transfer device **10** is adapted to receive a sample **12** therein via the inlet **28.** After the sample **12** enters the specimen mixing and transfer device **10** via the inlet **28,** the sample **12** flows through the inlet channel **32** to the mixing chamber **36.**

[0031] With the sample **12** received within the mixing chamber **36,** the mixing chamber **36** acts as a flow-through chamber for the effective mixing of a sample **12** with the dry anticoagulant powder **20** within the material **16.** In other embodiments, the material **16** may contain other dry substances. The effective mixing is achieved by passing the sample 12 through the material **16** having the dry anticoagulant powder **20** distributed throughout its microstructure. The sample **12** dissolves and mixes with the dry anticoagulant powder **20** while passing through the material **16.**

[0032] Referring to **Fig. 2,** a view of the microstructure of the material **16** having a dry anticoagulant powder **20** distributed throughout its microstructure, e.g., its pores **18,** is illustrated.

[0033] Referring to **Fig. 3,** in one embodiment, the housing **14** of the specimen mixing and transfer device **10** includes a dispensing chamber or holding chamber **38.** The dispensing chamber **38** may be adjacent the outlet **30** of the specimen mixing and transfer device **10.** For example, the dispensing chamber **38** may be disposed between the mixing chamber **36** and the outlet **30.**

[0034] After the blood sample is exposed to and mixes with the anticoagulant powder **20** while passing through the intricate microstructure of the material **16,** a stabilized sample flows from the material **16** to the dispensing chamber **38** via the outlet channel **34.** The stabilized sample can remain within the dispensing chamber **38** until it is desired to transfer the stabilized sample from the specimen mixing and transfer device **10.** For example, the stabilized sample may be transferred to a diagnostic instrument such as a blood testing device, a point-of-care testing device, or similar analytical device.

[0035] **Figs. 4-10** illustrate other exemplary configuration of a specimen mixing and transfer device of the present disclosure. Referring to **Figs. 4-10,** a specimen mixing and transfer device of the present disclosure may also be effective with small blood volumes that are typically associated with laminar flow conditions that require flow obstacles to promote mixing with a dry anticoagulant deposited on the walls of the flow-through structure.

[0036] **Figs. 4-6** illustrate another exemplary configuration of a specimen mixing and transfer device of the present disclosure. The specimen mixing and transfer device **100** is adapted to receive a sample **112.** In some configurations, the sample **112** may be a blood sample. In one configuration, the specimen mixing and transfer device **100** includes a housing **114,** a dry anticoagulant powder **120** disposed within the housing **114,** and a mixing element **115** disposed within the housing **114.**

[0037] The housing **114** includes a first end **122,** a second end **124,** and a sidewall **126** extending between the first end **122** and the second end **124.** In one configuration, the first end **122** includes an inlet **128** and the second end **124** includes an outlet **130.**

[0038] Referring to **Fig. 5,** in one configuration, the housing **114** of the specimen mixing and transfer device **100** includes an inlet channel **132** and an outlet channel **134.** The inlet channel **132** and the outlet channel **134** are in fluid communication via a flow channel or mixing chamber **136.** For example, the inlet channel **132** is in fluid communication with the inlet **128** and the mixing chamber **136;** and the outlet channel **134** is in fluid communication with the mixing chamber **136** and the outlet **130.** In one configuration, the dry anticoagulant powder **120** is disposed within the mixing chamber **136** of the housing **114.**

[0039] In one configuration, the inlet channel **132** and the outlet channel **134** are in fluid communication via a first flow channel **140** and a second flow channel **142.** For example, the inlet channel **132** may branch off into two separate flow channels, e.g., the first flow channel 140 and the second flow channel **142.** The two separate flow channels, e.g., the first flow channel **140** and the second flow channel **142,** may both flow into the outlet channel **134** as shown in **Fig. 5.**

[0040] The first flow channel **140** includes walls **144** and the second flow channel **142** includes walls **146.** In one configuration, a first portion of the dry anticoagulant powder **120** is deposited on walls **144** and a second portion of the dry anticoagulant powder **120** is deposited on walls **146.** For example, in one configuration, a first portion of the dry anticoagulant powder **120** is deposited on an interior surface **148** of the housing **114,** e.g., an interior surface of wall **144,** and a second portion of the dry anticoagulant powder **120** is deposited on an interior surface **148** of the housing **114,** e.g., an interior surface of wall **146.**

[0041] Referring to **Fig. 5,** in one configuration, the housing **114** of the specimen mixing and transfer device **100** includes a dispensing chamber or holding chamber **138.** The dispensing chamber **138** may be adjacent to the outlet **130** of the specimen mixing and transfer device **100.** For example, the dispensing chamber **138** may be disposed between the mixing chamber **136** and the outlet **130.** In one embodiment, the dispensing chamber **138** may be positioned between the flow channels **140, 142** and the outlet **130.**

[0042] In one configuration, the specimen mixing and transfer device **100** includes a mixing element **115** disposed within the housing **114.** For example, a portion of the mixing chamber **136** may also include obstacles or mixing promoters **150** that interfere with the flow path of the blood sample thereby promoting mixing between the blood sample and the dry anticoagulant powder **120.** In some configurations, a portion of the first flow channel **140** and a portion of the second flow channel **142** may include obstacles or mixing promoters **150** that interfere with the flow path of the blood sample thereby promoting mixing between the blood sample and the dry anticoagulant powder **120.**

[0043] Referring to **Figs. 4-6,** the specimen mixing and transfer device **100** is adapted to receive a sample **112** therein via the first end **122.** For example, the housing **114** of the specimen mixing and transfer device **100** is adapted to receive a sample **112** therein via the inlet **128.** The sample **112** flows into the inlet **128** and to the inlet channel **132.** In some embodiments, the sample **112** may be a blood sample.

[0044] With the blood sample received within the inlet channel **132,** a first portion **152** of the blood sample flows to the first flow channel **140** and a second portion **154** of the blood sample flows to the second flow channel **142.** The first flow channel **140** provides a first flow path for the first portion **152** of the blood sample and the second flow channel **142** provides a second flow path for the second portion **154** of the blood sample.

[0045] With the first portion **152** of the blood sample received within the first flow channel **140,** the first portion **152** of the blood sample mixes with a first portion of the dry anticoagulant powder **120** deposited on the walls **144** of the first flow channel **140.** The first flow channel **140** may also include obstacles or mixing promoters **150** that interfere with the flow path of the blood sample thereby promoting mixing between the blood sample and the first portion of the dry anticoagulant powder **120.** After mixing, the first portion **152** of the blood sample and the first portion of the dry anticoagulant powder **120,** i.e., a stabilized blood sample, travel to the outlet channel **134.**

[0046] With the second portion **154** of the blood sample received within the second flow channel **142,** the second portion **154** of the blood sample mixes with a second portion of the dry anticoagulant powder **120** deposited on the walls **146** of the second flow channel **142.** The second flow channel **142** may also include obstacles or mixing promoters **150** that interfere with the flow path of the blood sample thereby promoting mixing between the blood sample and the second portion of the dry anticoagulant powder **120.** After mixing, the second portion **154** of the blood sample and the second portion of the dry anticoagulant powder **120,** i.e., a stabilized blood sample, travel to the outlet channel **134.**

[0047] In other configurations, other portions of the specimen mixing and transfer device 100 may also include obstacles or mixing promoters **150** that interfere with the flow path of the blood sample thereby promoting mixing between the blood sample and the dry anticoagulant powder **120.**

[0048] **Figs. 7-10** illustrate other exemplary configurations of a specimen mixing and transfer device of the present disclosure. Referring to **Figs. 7 and 8,** the specimen mixing and transfer device **200** is adapted to receive a sample **212.** In some configurations, the sample **212** may be a blood sample. In one configuration, the specimen mixing and transfer device **200** includes a housing **214,** a dry anticoagulant powder **220** disposed within the housing **214,** and a mixing element **215** disposed within the housing **214.**

[0049] The housing **214** includes a first end **222,** a second end **224,** and a sidewall **226** extending between the first end **222** and the second end **224.** In one configuration, the first end **222** includes an inlet **228** and the second end **224** includes an outlet **230.**

[0050] Referring to **Fig. 8,** in one configuration, the housing **214** of the specimen mixing and transfer device **200** includes an inlet channel **232** and an outlet channel **234.** The inlet channel **232** and the outlet channel **234** are in fluid communication via a flow channel or mixing chamber **236.** For example, the inlet channel **232** is in fluid communication with the inlet **228** and the mixing chamber **236;** and the outlet channel **234** is in fluid communication with the mixing chamber **236** and the outlet **230.** In one embodiment, the dry anticoagulant powder **220** is disposed within the mixing chamber **236** of the housing **214.** In one configuration, the dry anticoagulant powder **220** is deposited on an interior surface **260** of the housing **214.**

[0051] Referring to **Fig. 8,** in one configuration, the housing **214** of the specimen mixing and transfer device **200** includes a dispensing chamber or holding chamber **238.** The dispensing chamber **238** may be adjacent to the outlet **230** of the specimen mixing and transfer device **200.** For example, the dispensing chamber **238** may be disposed between the mixing chamber **236** and the outlet **230.**

[0052] In one configuration, the specimen mixing and transfer device **200** includes a mixing element **215** disposed within the housing **214.** In one configuration, the mixing element **215** includes a plurality of posts **270.** For example, the mixing chamber **236** may include a plurality of posts **270** that interfere with the flow path of the blood sample thereby promoting mixing between the blood sample and the dry anticoagulant powder **220.**

[0053] Referring to **Figs. 7 and 8,** the specimen mixing and transfer device **200** is adapted to receive a sample **212** therein via the first end **222.** For example, the housing **214** of the specimen mixing and transfer device **200** is adapted to receive a sample **212** therein via the inlet **228.** The sample **212** flows into the inlet **228** and to the inlet channel **232.** In some configurations, the sample **212** may be a blood sample.

[0054] With the blood sample received within the inlet channel **232,** the blood sample flows into the mixing chamber **236.** As the blood sample flows into the mixing chamber **236,** the blood sample mixes with the dry anticoagulant powder **220** deposited on an interior surface **260** of the housing **214.** The mixing chamber **236** may include the plurality of posts **270** that interfere with the flow path of the blood sample thereby promoting mixing between the blood sample and the dry anticoagulant powder **220.** After mixing, the blood sample and the dry anticoagulant powder **220,** i.e., a stabilized blood sample, travel to the outlet channel **234.**

[0055] In other configurations, other portions of the specimen mixing and transfer device 200 may also include mixing elements **215** that interfere with the flow path of the blood sample thereby promoting mixing between the blood sample and the dry anticoagulant powder **220.**

[0056] Referring to **Fig. 10,** alternate configurations of a specimen mixing and transfer device of the present disclosure are illustrated.

[0057] **Figs. 11A-16** illustrate another exemplary embodiment of a material of the present disclosure. The material **502** includes pores **505** and has a dry anticoagulant powder **504** within the pores **505** of the material **502,** as described above. In one embodiment, the material **502** is a sponge material. In other embodiments, the material **502** is an open cell foam. In one embodiment, the open cell foam is treated with an anticoagulant, as described in detail above, to form a dry anticoagulant powder **504** finely distributed throughout the pores **505** of the material **502.**

[0058] In one embodiment, the material **502** is an open cell foam. For example, the material 502 is a soft deformable open cell foam that is inert to blood. In one embodiment, the open cell foam may be a melamine foam, such as Basotect® foam commercially available from BASF. In another embodiment, the open cell foam may consist of a formaldehyde-melamine-sodium bisulfite copolymer. The open cell foam may be a flexible, hydrophilic open cell foam that is resistant to heat and many organic solvents. In one embodiment, the open cell foam may be a sponge material.

[0059] Referring to **Figs. 11A-16,** the material **502** can be utilized with a syringe assembly 500. The syringe assembly **500** may include an open cell foam material **502** having a dry anticoagulant powder **504** therein. The open cell foam material **502** is disposed within the syringe assembly **500.** The anticoagulant can be loaded into the open cell foam material **502** having pores **505,** as described above.

[0060] In one embodiment, the syringe assembly **500**

includes a syringe barrel **506** having a first end **508,** a second end **510,** and a sidewall **512** extending therebetween and defining an interior **514.** Referring to **Figs. 11A-11C and 15,** the open cell foam material **502** is disposed within the interior **514** of the syringe barrel **506.**

[0061] In one embodiment, the syringe assembly **500** includes a plunger rod **516** and a stopper 518. The plunger rod **516** includes a first end **520** and a second end **522.** The stopper **518** is engaged with the second end **522** of the plunger rod **516** and is slidably disposed within the interior **514** of the syringe barrel **506.** The stopper **518** is sized relative to the interior **514** of the syringe barrel **506** to provide sealing engagement with the sidewall **512** of the syringe barrel **506.**

[0062] The open cell foam material **502** is placed in the syringe barrel **506** for mixing and stabilizing blood. The blood gets collected in the syringe barrel **506** with the open cell foam material **502** embedded inside the syringe barrel **506.** The stabilized blood can then be dispensed for analysis. In one embodiment, the syringe assembly **500** is an arterial blood gas syringe and the stabilized blood can be dispensed for blood gas analysis.

[0063] In one embodiment, the syringe assembly **500** acts as a flow-through chamber for the effective mixing of a blood sample with the dry anticoagulant powder **504** within the open cell foam material **502.** In other embodiments, the open cell foam material **502** may contain other dry substances. The effective mixing is achieved by passing the blood sample through the open cell foam material **502** having the dry anticoagulant powder **504** distributed throughout its microstructure.

[0064] Referring to **Fig. 13,** a view of the microstructure of the open cell foam material **502** having a dry anticoagulant powder **504** distributed throughout its microstructure is illustrated. Referring to **Fig. 14,** a view of the microstructure of an untreated foam material **502** is illustrated. Referring to **Fig. 16,** a graph is illustrated demonstrating the anticoagulant uptake by a blood sample flowing through an open cell foam material having a dry anticoagulant powder distributed throughout its microstructure.

[0065] **Figs. 17-20** illustrate an exemplary embodiment of a specimen mixing and transfer system of the present disclosure. Referring to **Figs. 17-20,** in one embodiment, a blood transfer system **600** includes a syringe assembly **602,** a line **604,** and a container **606.** In one embodiment, the container **606** contains blood **608.**

[0066] In one embodiment, the line **604** includes an open cell foam material **612** having a dry anticoagulant powder **614** therein. The anticoagulant can be loaded into the open cell foam material **612** having pores, as described above. The open cell foam material **612** is disposed within the line **604.** The line **604** includes a first end **616** and a second end **618.**

[0067] In one embodiment, the syringe assembly **602** includes a syringe barrel **620** and a sidewall **622** defining an interior **624.** Referring to **Figs. 17-20,** the line **604** is adapted to place the syringe assembly **602** and the container **606** in fluid communication. For example, the first end **616** of the line **604** can be in fluid communication with the contents of the container **606,** and the second end **618** of the line **604** can be in fluid communication with the syringe assembly **602.**

[0068] The open cell foam material **612** is placed in the line **604** for mixing and stabilizing blood. In one embodiment, the blood **608** is transferred from the container **606** to the syringe barrel **620** via the line **604.** For example, a blood sample, e.g., blood **608,** passes through the line **604** with the open cell foam material **612** embedded inside the line **604** as the blood gets collected into the syringe barrel **620.** In this manner, the blood **608** is stabilized before entering the syringe barrel **620.** After the stabilized blood **608** is contained within the syringe barrel **620,** the stabilized blood **608** can then be dispensed for analysis.

[0069] In one embodiment, the line **604** acts as a flow-through chamber for the effective mixing of a blood sample with the dry anticoagulant powder **614** within the open cell foam material **612.** In other embodiments, the open cell foam material **612** may contain other dry substances. The effective mixing is achieved by passing the blood sample through the open cell foam material **612** having the dry anticoagulant powder **614** distributed throughout its microstructure.

[0070] The present disclosure provides a material that includes pores and has a dry anticoagulant powder within the pores of the material, as described above. In one embodiment, the material is a sponge material. In other embodiments, the material is an open cell foam. In one embodiment, the open cell foam is treated with an anticoagulant, as described in detail above, to form a dry anticoagulant powder finely distributed throughout the pores of the material.

[0071] The present disclosure provides different applications and embodiments of the material. For example, in one embodiment, a specimen mixing and transfer device of the present disclosure is adapted to receive a sample. The specimen mixing and transfer device includes a housing, a material including pores that is disposed within the housing, and a dry anticoagulant powder within the pores of the material. In one embodiment, the material is a sponge material. In other embodiments, the material is an open cell foam. In one embodiment, the open cell foam is treated with an anticoagulant to form a dry anticoagulant powder finely distributed throughout the pores of the material. A blood sample may be received within the specimen mixing and transfer device. The blood sample is exposed to and mixes with the anticoagulant powder while passing through the material.

[0072] A specimen mixing and transfer device of the present disclosure offers uniform and passive blood mixing with an anticoagulant under flow-through conditions. A specimen mixing and transfer device of the present disclosure could catch blood clots or other contaminants within the microstructure of the material and prevent them from being dispensed into a diagnostic sample port. A specimen mixing and transfer device of the present disclosure enables a simple, low-cost design for passive flow-through blood stabilization. A specimen mixing and transfer device of the present disclosure enables precisely controlled loading of an anticoagulant into the material by soaking it with an anticoagulant and water solution and then drying the material to form a finely distributed dry anticoagulant powder throughout the pores of the material.

[0073] A specimen mixing and transfer device of the present disclosure may provide an effective passive blood mixing solution for applications wherein blood flows through a line. Such a specimen mixing and transfer device is useful for small blood volumes, e.g., less than 50 μL or less than 500 μL, and/or where inertial, e.g., gravity based, forces are ineffective for bulk manual mixing by flipping back and forth a blood collection container such as is required for vacuum tubes.

[0074] In other embodiments of the present disclosure, the material can be utilized with a specimen mixing and transfer system or a syringe assembly, as described above.

Claims

1. A specimen mixing and transfer device (10) adapted to receive a fluid sample (12), **characterized in that** the device comprises:

    a housing (14) having a first end (22) including an inlet (28), a second end (24) including an outlet (30), and a sidewall (26) extending therebetween;
    a material (16) including pores (18) and disposed within the housing (14);
    a dry anticoagulant powder (20) within the pores (18) of the material (16); and
    a mixing chamber (36), wherein the material (16) is disposed within the mixing chamber (36);
    wherein the housing (14) further comprises an inlet channel (32) in fluid communication with the inlet (28) and the mixing chamber (36) and an outlet channel (34) in fluid communication with the mixing chamber (36) and the outlet (30);
    characterized by
    a dispensing chamber (38) between the mixing chamber (36) and the outlet (30), the dispensing chamber (38) being configured to hold the stabilized sample (12) until it is desired to transfer the stabilized sample (12) from the specimen mixing and transfer device (10),
    wherein the material (16) is a melamine open cell foam.

2. The specimen mixing and transfer device (10) of claim 1, wherein the sample (12) is a blood sample.

3. The specimen mixing and transfer device (10) of claim 2, wherein the housing (14) is adapted to receive the blood sample therein via the first end (22).

4. The specimen mixing and transfer device (10) of claim 3, wherein the housing (14) is configured to enable the blood sample to pass through the material (16) to effectively mix the blood sample with the dry anticoagulant powder (20).

5. The specimen mixing and transfer device (10) of claim 4, wherein the material (16) is configured such that the blood sample dissolves and mixes with the dry anticoagulant powder (20) while passing through the material (16).

Patentansprüche

1. Probenmisch- und -übertragungsvorrichtung (10) zum Aufnehmen einer Fluidprobe (12), **dadurch gekennzeichnet, dass** die Vorrichtung aufweist:

    ein Gehäuse (14) mit einem ersten Ende (22), das einen Einlass (28) aufweist, einem zweiten Ende (24), das einen Auslass (30) aufweist, und einer sich zwischen diesen erstreckenden Seitenwand (26);
    ein Material (16), das Poren (18) aufweist und in dem Gehäuse (14) angeordnet ist;
    ein trockenes Antikoagulanspulver (20) in den Poren (18) des Materials (16); und
    eine Mischkammer (36), wobei das Material (16) in der Mischkammer (36) angeordnet ist;
    wobei das Gehäuse (14) ferner einen Einlasskanal (32) in Fluidverbindung mit dem Einlass (28) und der Mischkammer (36) und einen Auslasskanal (34) in Fluidverbindung mit der Mischkammer (36) und dem Auslass (30) aufweist,
    gekennzeichnet durch
    eine Ausgabekammer (38) zwischen der Mischkammer (36) und dem Auslass (30), wobei die Ausgabekammer (38) dazu ausgebildet ist, die stabilisierte Probe (12) aufzunehmen, bis das Übertragen der stabilisierten Probe (12) von der Probenmisch- und -übertragungsvorrichtung (10) gewünscht wird,
    wobei das Material (16) ein offenporiger Melaminschaum ist.

2. Probenmisch- und -übertragungsvorrichtung (10) nach Anspruch 1, bei welcher die Probe (12) eine Blutprobe ist.

3. Probenmisch- und -übertragungsvorrichtung (10) nach Anspruch 2, bei welcher das Gehäuse (14) geeignet ist, die Blutprobe über das erste Ende (22) aufzunehmen.

4. Probenmisch- und -übertragungsvorrichtung (10) nach Anspruch 3, bei welcher das Gehäuse (14) dazu ausgebildet ist, den Durchtritt der Blutprobe durch das Material (16) zu ermöglichen, um die Blutprobe effektiv mit dem trockenen Antikoagulanspulver (20) zu mischen.

5. Probenmisch- und -übertragungsvorrichtung (10) nach Anspruch 4, bei welcher das Material (16) derart ausgebildet ist, dass sich die Blutprobe auflöst und mit dem trockenen Antikoagulanspulver (20) mischt, während sie durch das Material (16) tritt.

Revendications

1. Dispositif de mélange et de transfert de spécimen (10) adapté pour recevoir un échantillon de fluide (12), **caractérisé en ce que** le dispositif comprend :

un boîtier (14) ayant une première extrémité (22) comportant une entrée (28), une deuxième extrémité (24) comportant une sortie (30), et une paroi latérale (26) s'étendant entre elles ;
un matériau (16) comportant des pores (18) et disposé à l'intérieur du boîtier (14) ;
une poudre anticoagulante sèche (20) à l'intérieur des pores (18) du matériau (16) ; et
une chambre de mélange (36), où le matériau (16) est disposé à l'intérieur de la chambre de mélange (36) ;
dans lequel le boîtier (14) comprend en outre un canal d'entrée (32) en communication fluidique avec l'entrée (28) et la chambre de mélange (36) et un canal de sortie (34) en communication fluidique avec la chambre de mélange (36) et la sortie (30) ;
caractérisé par
une chambre de distribution (38) entre la chambre de mélange (36) et la sortie (30), la chambre de distribution (38) étant configurée pour contenir l'échantillon stabilisé (12) jusqu'à ce que l'on souhaite transférer l'échantillon stabilisé (12) du dispositif de mélange et de transfert de spécimen (10),
dans lequel le matériau (16) est une mousse de mélamine à cellules ouvertes.

2. Dispositif de mélange et de transfert de spécimen (10) de la revendication 1, dans lequel l'échantillon (12) est un échantillon de sang.

3. Dispositif de mélange et de transfert de spécimen (10) de la revendication 2, dans lequel le boîtier (14) est adapté pour recevoir l'échantillon de sang dans celui-ci par l'intermédiaire de la première extrémité (22).

4. Dispositif de mélange et de transfert de spécimen (10) de la revendication 3, dans lequel le boîtier (14) est configuré pour permettre à l'échantillon de sang de passer à travers le matériau (16) pour mélanger efficacement l'échantillon de sang avec la poudre anticoagulante sèche (20).

5. Dispositif de mélange et de transfert de spécimen (10) de la revendication 4, dans lequel le matériau (16) est configuré de sorte que l'échantillon de sang se dissolve et se mélange avec la poudre anticoagulante sèche (20) tout en passant à travers le matériau (16).

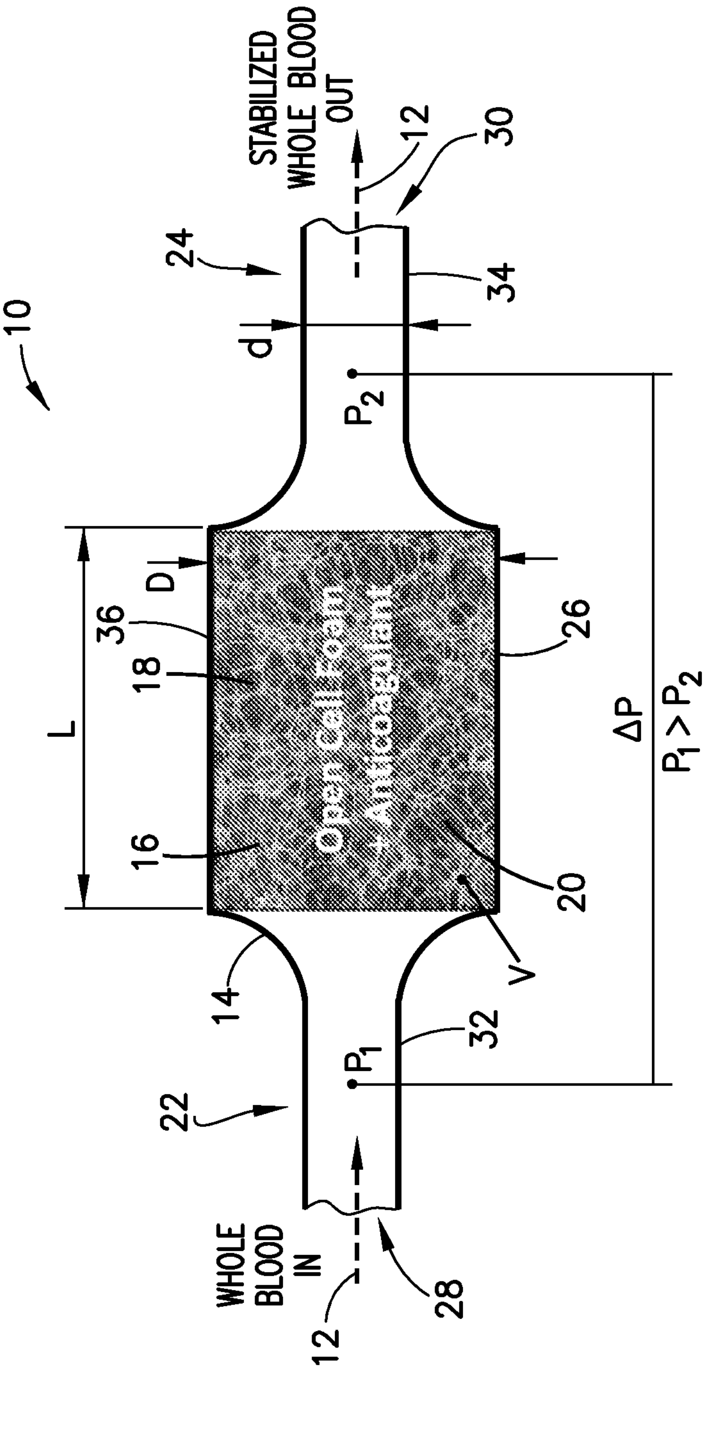
STABILIZED
WHOLE BLOOD
OUT
WHOLE
BLOOD
IN
Open Cell Foam
+ Anticoagulant
10
12
30
24
34
d
P2
D
36
18
26
L
16
20
V
14
32
P1
22
28
ΔP
P1 > P2

FIG. 1

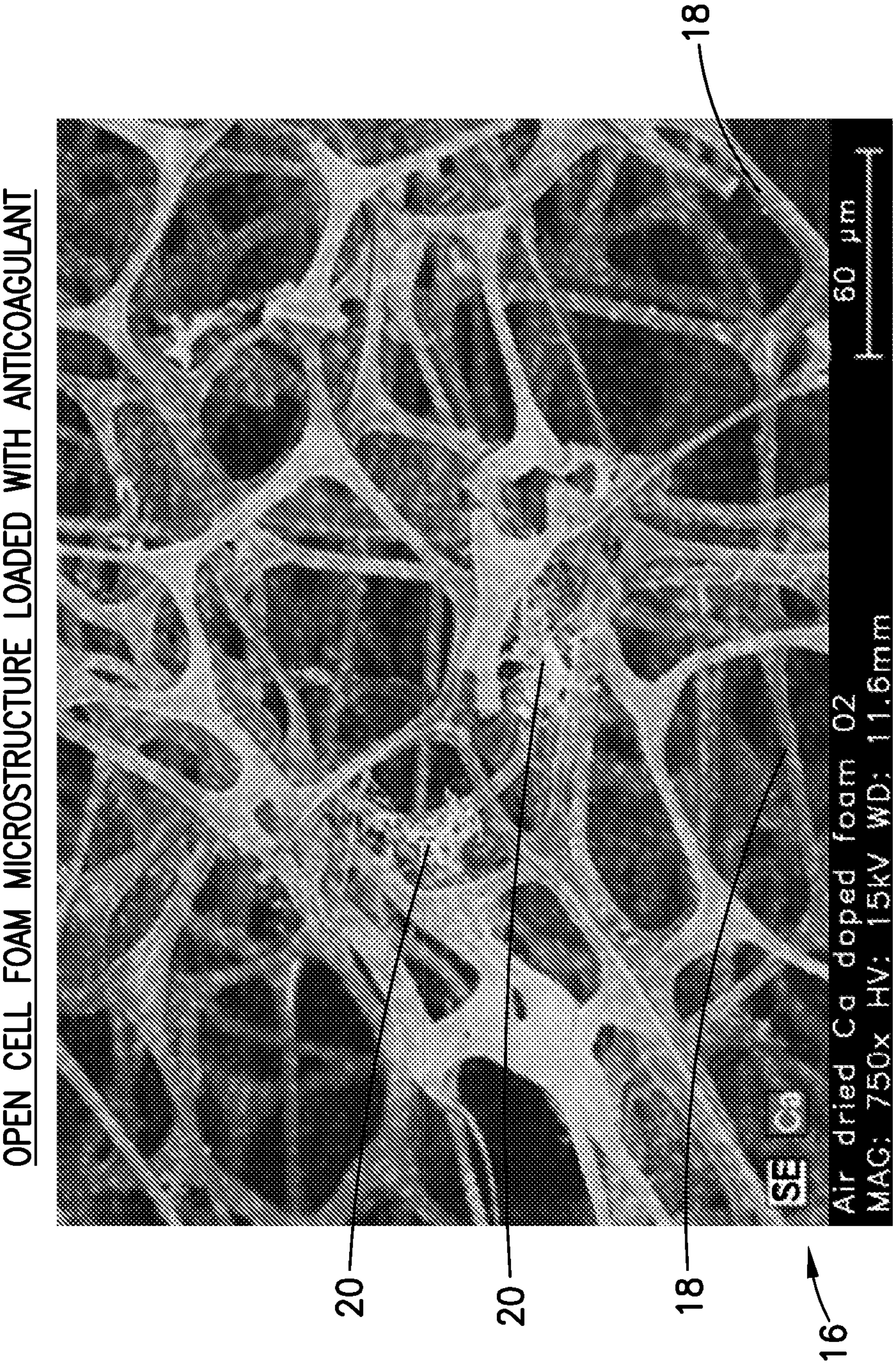
OPEN CELL FOAM MICROSTRUCTURE LOADED WITH ANTICOAGULANT
SE
Ca
Air dried Ca doped foam 02
MAG: 750x HV: 15kV WD: 11.6mm
60 μm
18
20
20
18
16

FIG.2

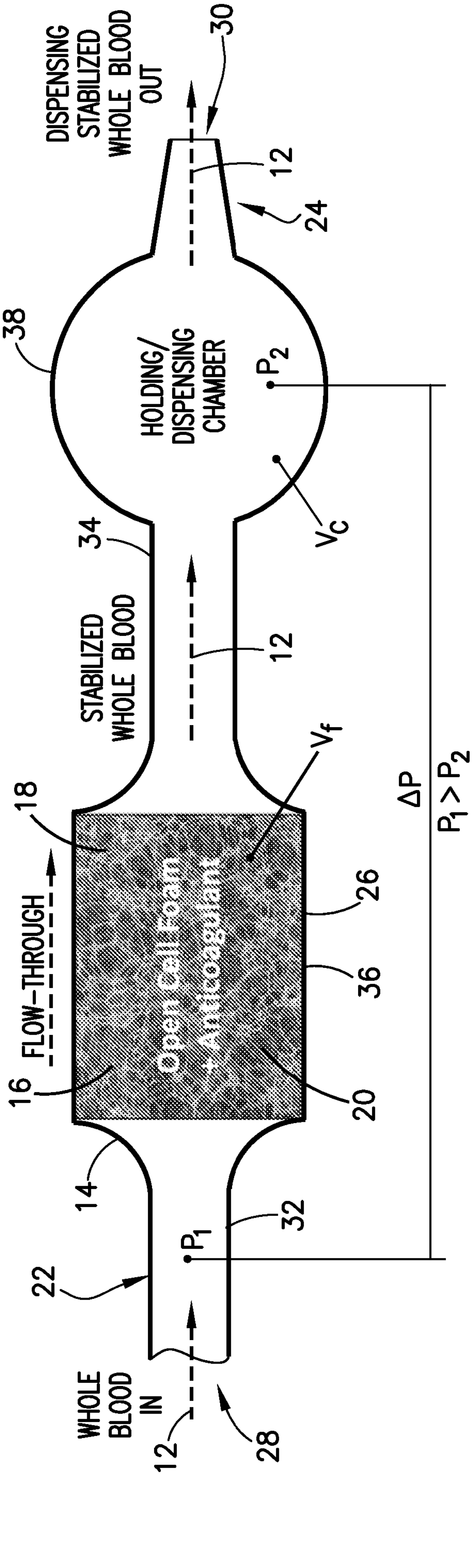
DISPENSING STABILIZED WHOLE BLOOD OUT
30
12
24
38
HOLDING/ DISPENSING CHAMBER
P2
VC
34
STABILIZED WHOLE BLOOD
12
10
Vf
18
FLOW-THROUGH
Open Cell Foam + Anticoagulant
26
36
16
20
14
32
P1
22
ΔP
P1 > P2
WHOLE BLOOD IN
12
28

FIG.3

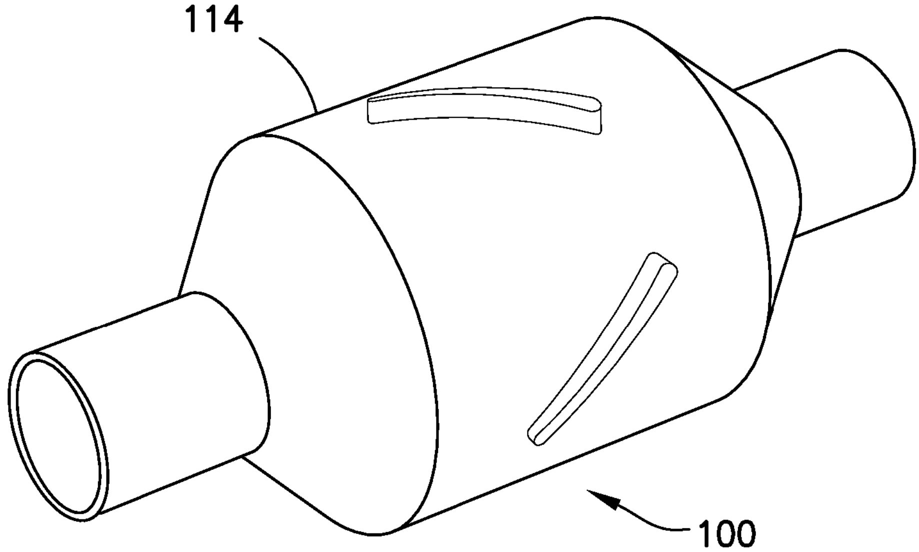

FIG.4

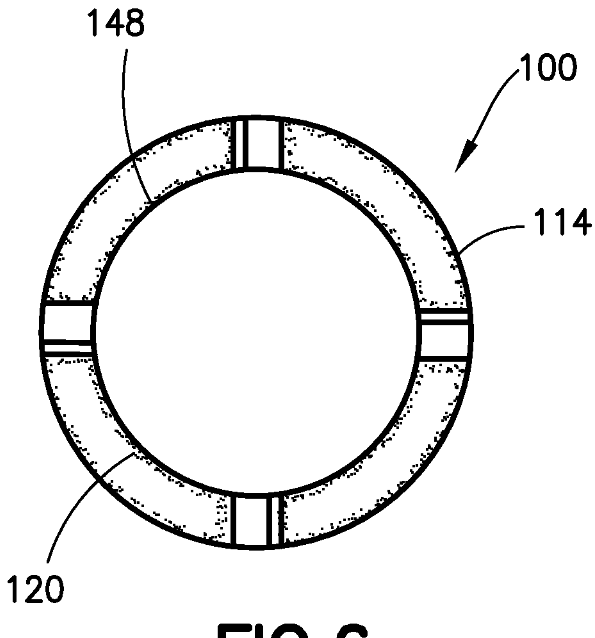

FIG.6

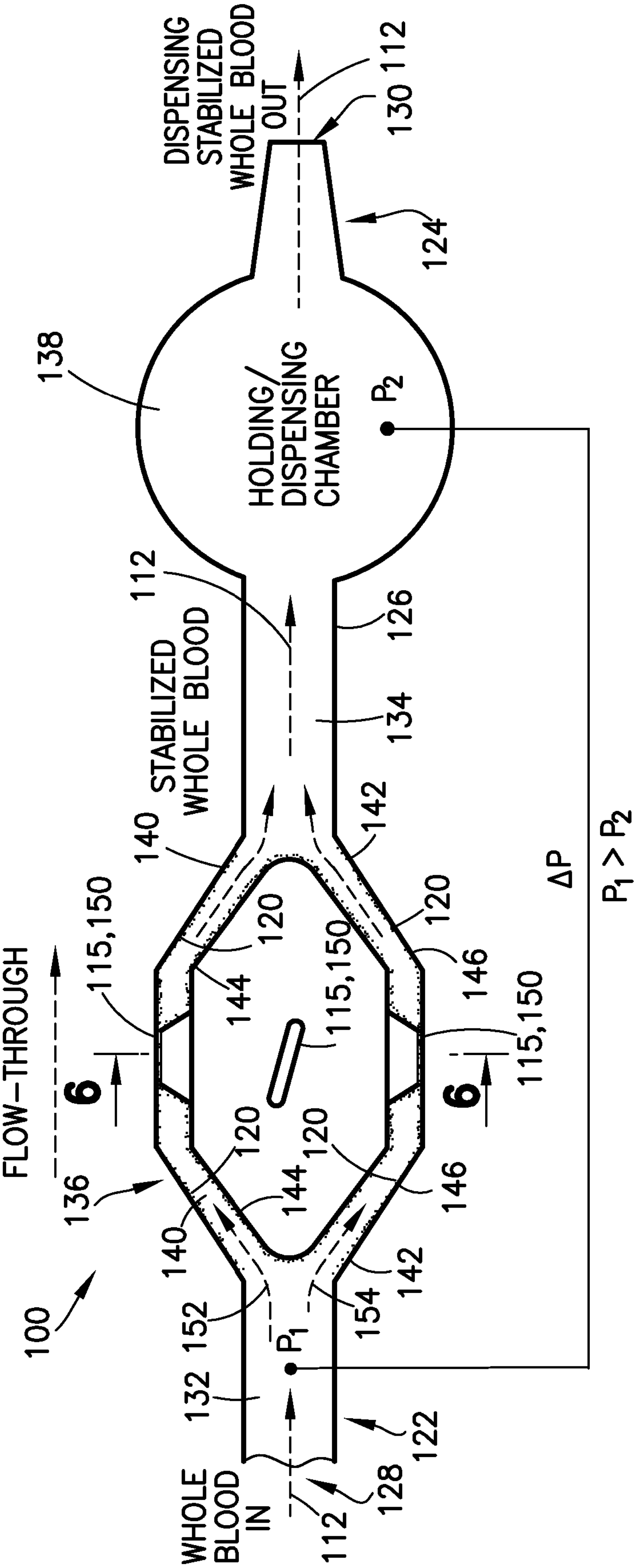
100
WHOLE BLOOD IN
112
128
122
132
P_1
152
154
140
142
136
FLOW-THROUGH
6
6
115,150
115,150
115,150
144
146
120
140
142
STABILIZED WHOLE BLOOD
112
134
126
HOLDING/ DISPENSING CHAMBER
P_2
138
124
130 112
DISPENSING STABILIZED WHOLE BLOOD OUT
ΔP
$P_1 > P_2$

FIG.5

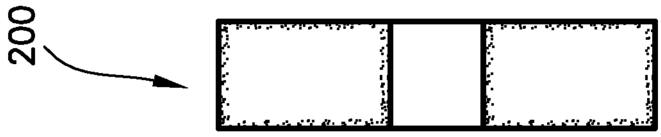

FIG.9

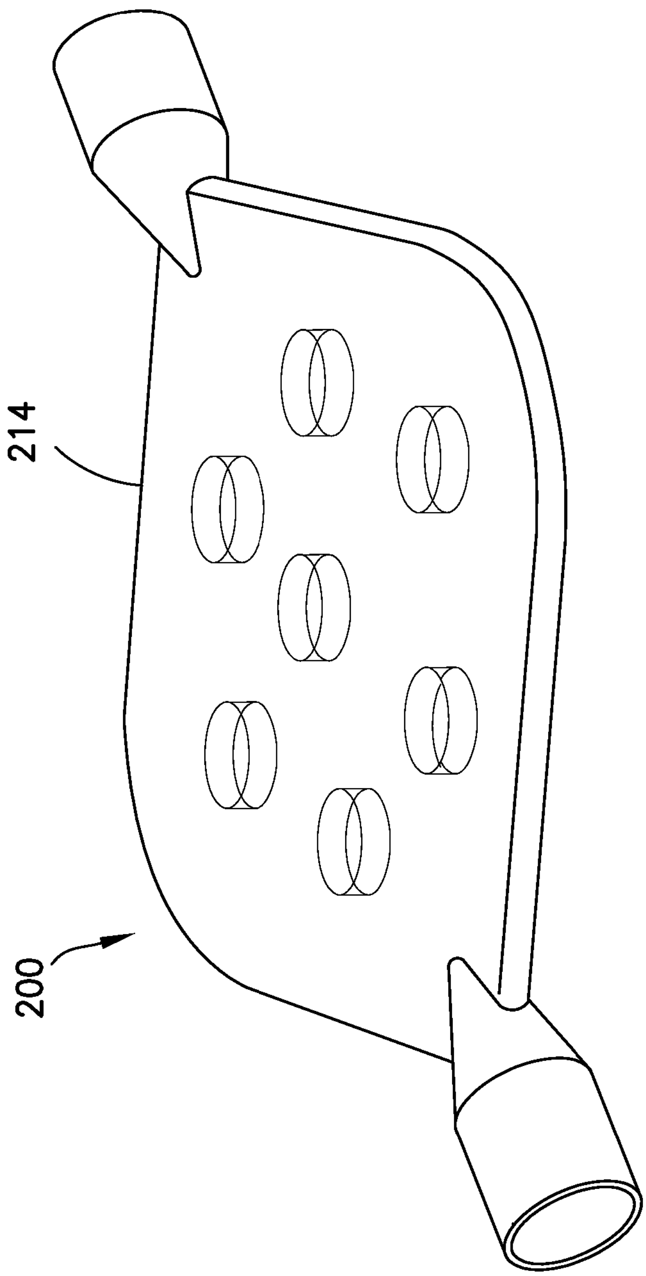

FIG.7

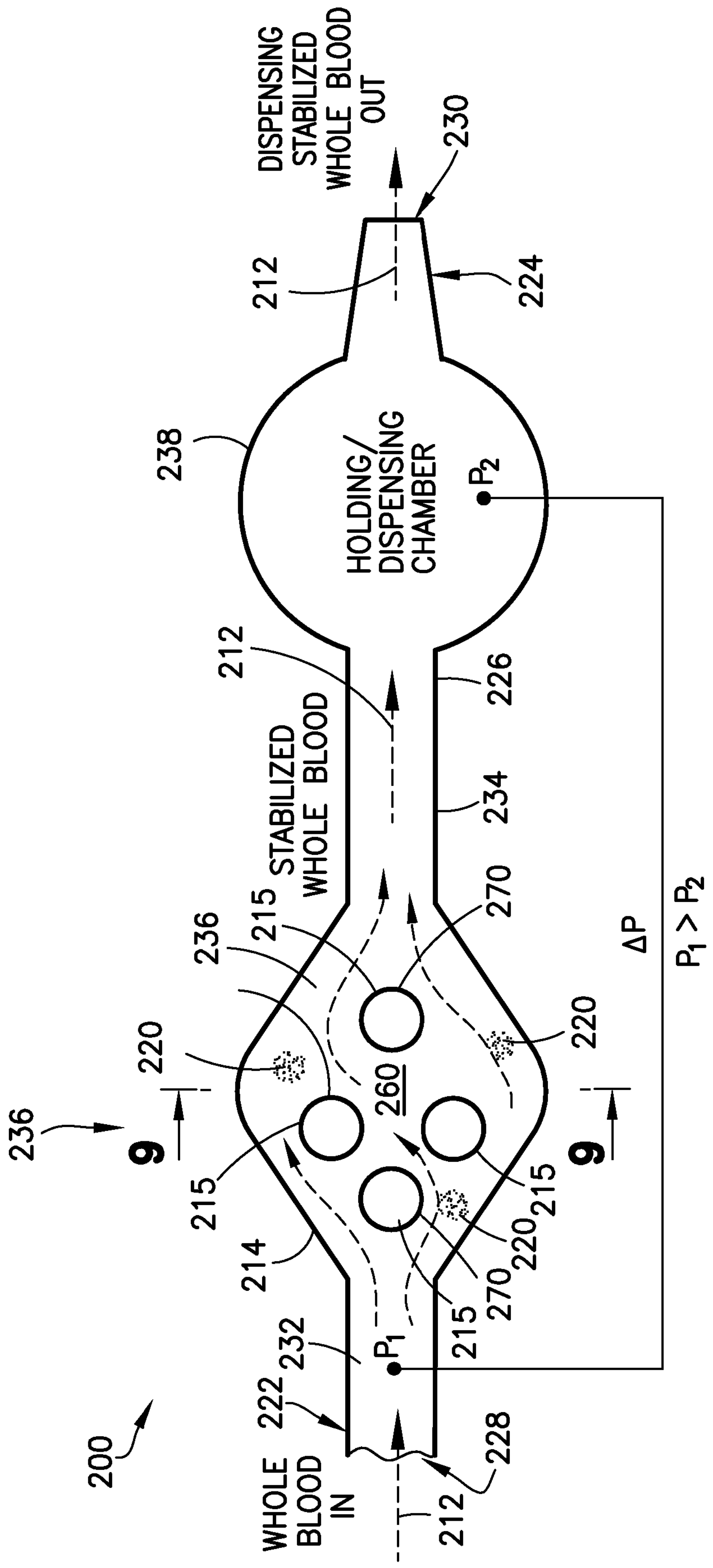
WHOLE BLOOD IN
STABILIZED WHOLE BLOOD
HOLDING/ DISPENSING CHAMBER
DISPENSING STABILIZED WHOLE BLOOD OUT
P_1
P_2
ΔP
$P_1 > P_2$
200
212
214
215
220
222
224
226
228
230
232
234
236
238
260
270
9

FIG.8

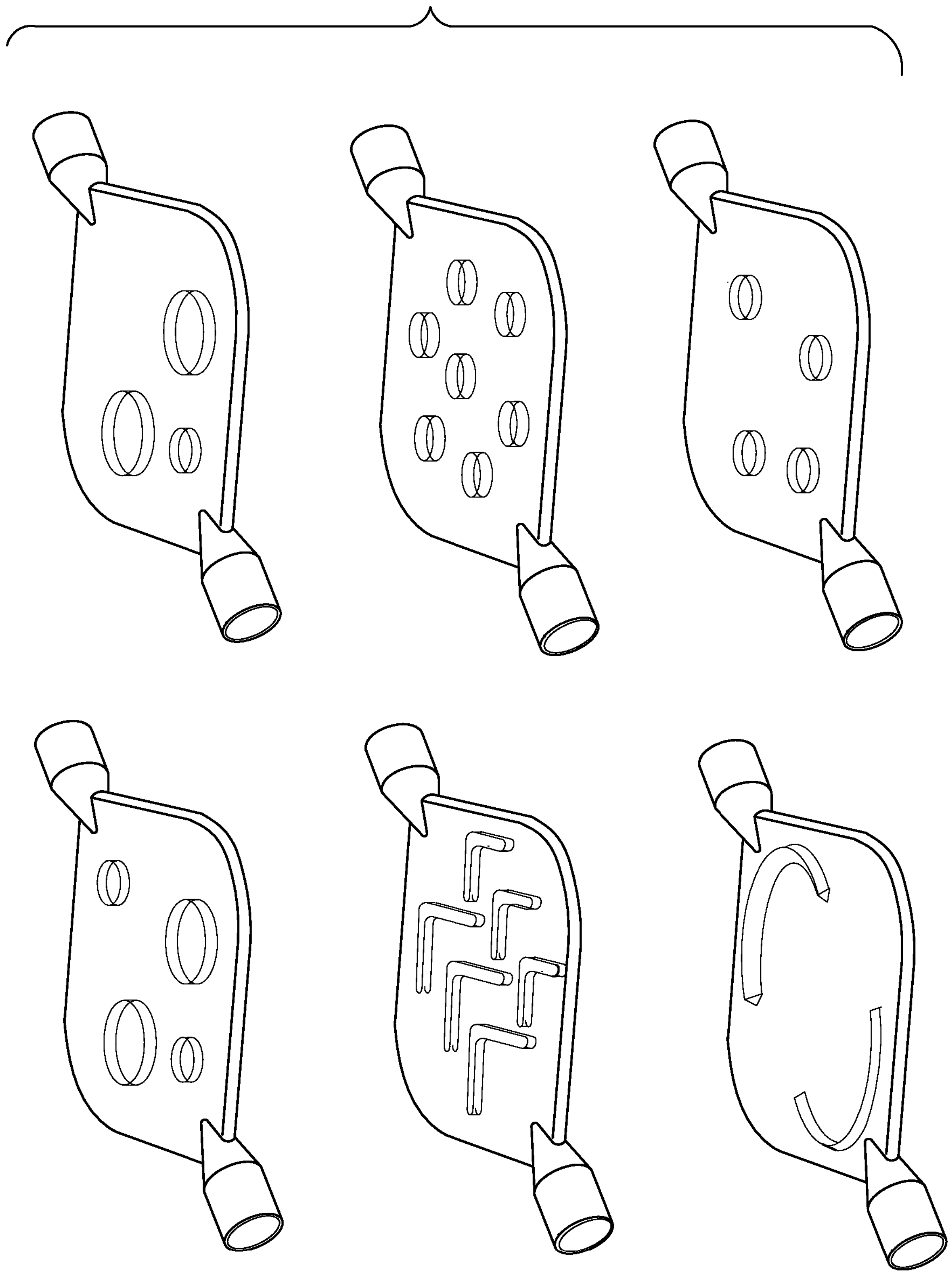

FIG.10

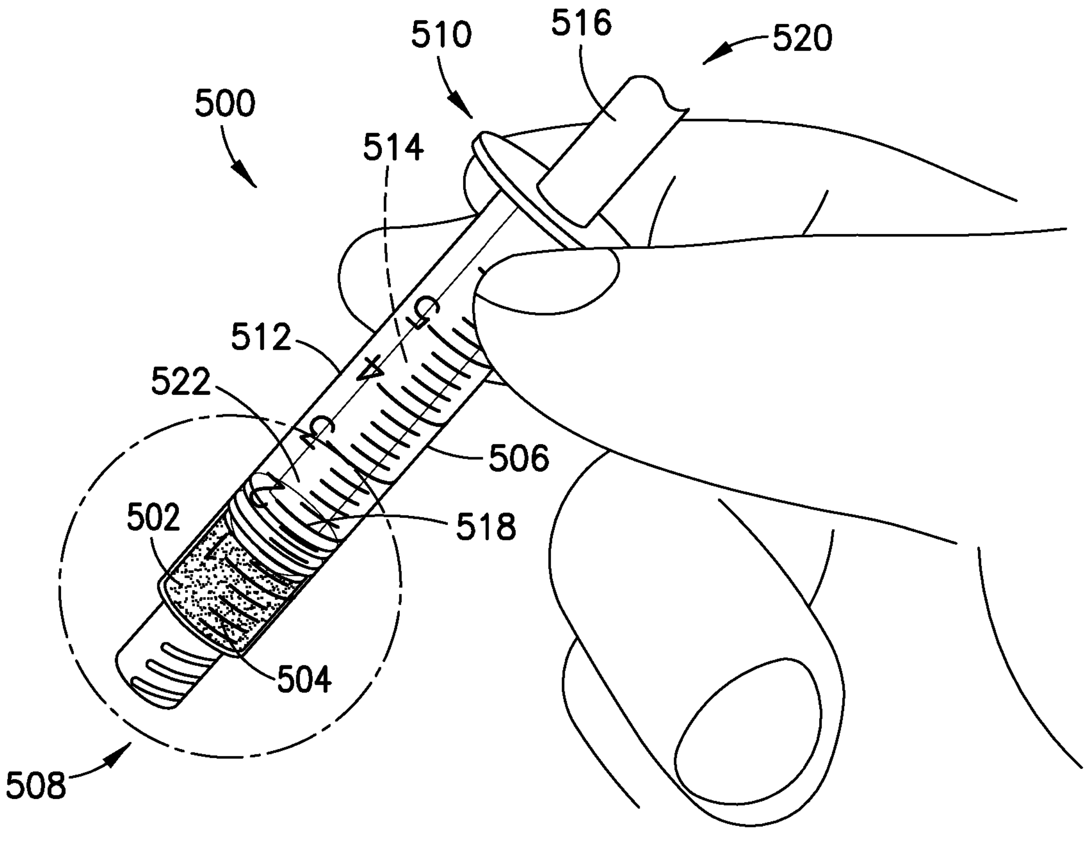

FIG.11A

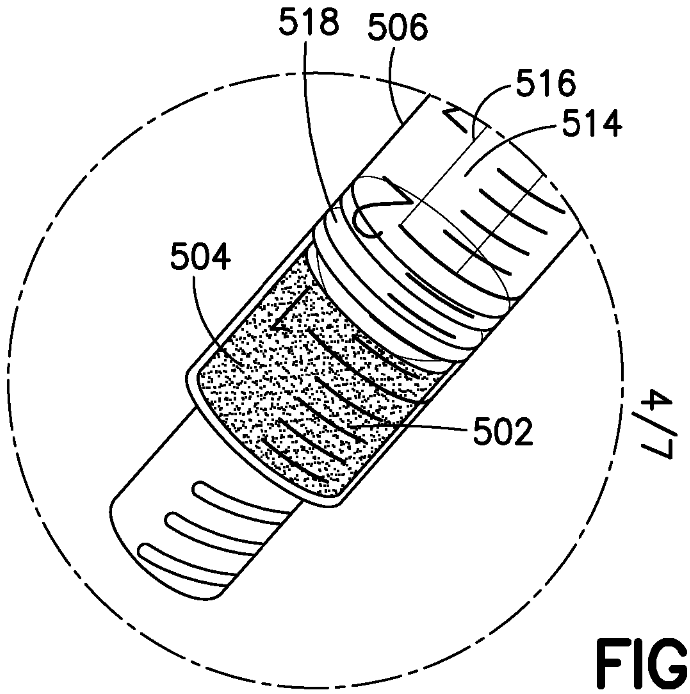

FIG.11B

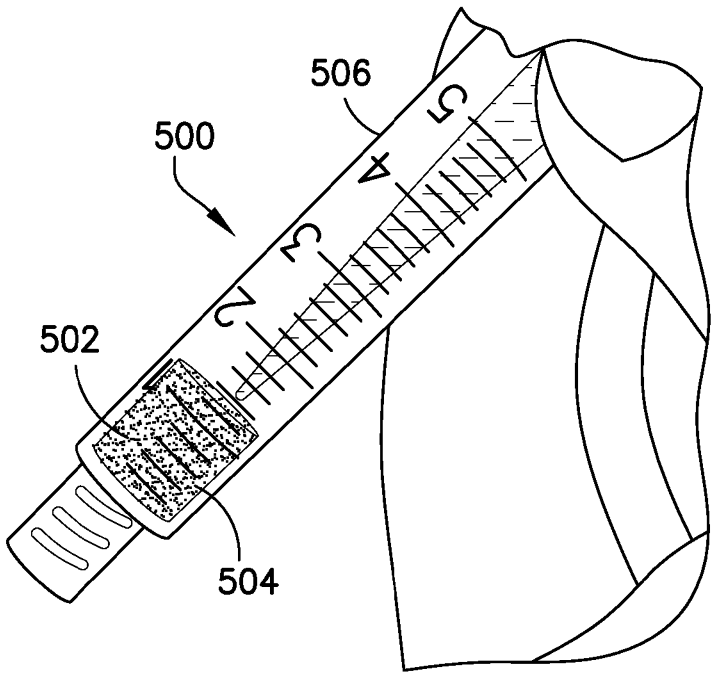

FIG.11C

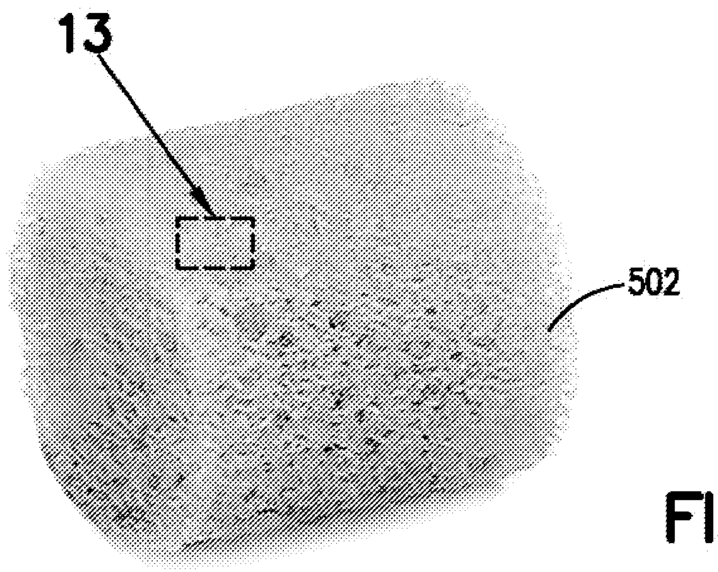
13
502

FIG.12

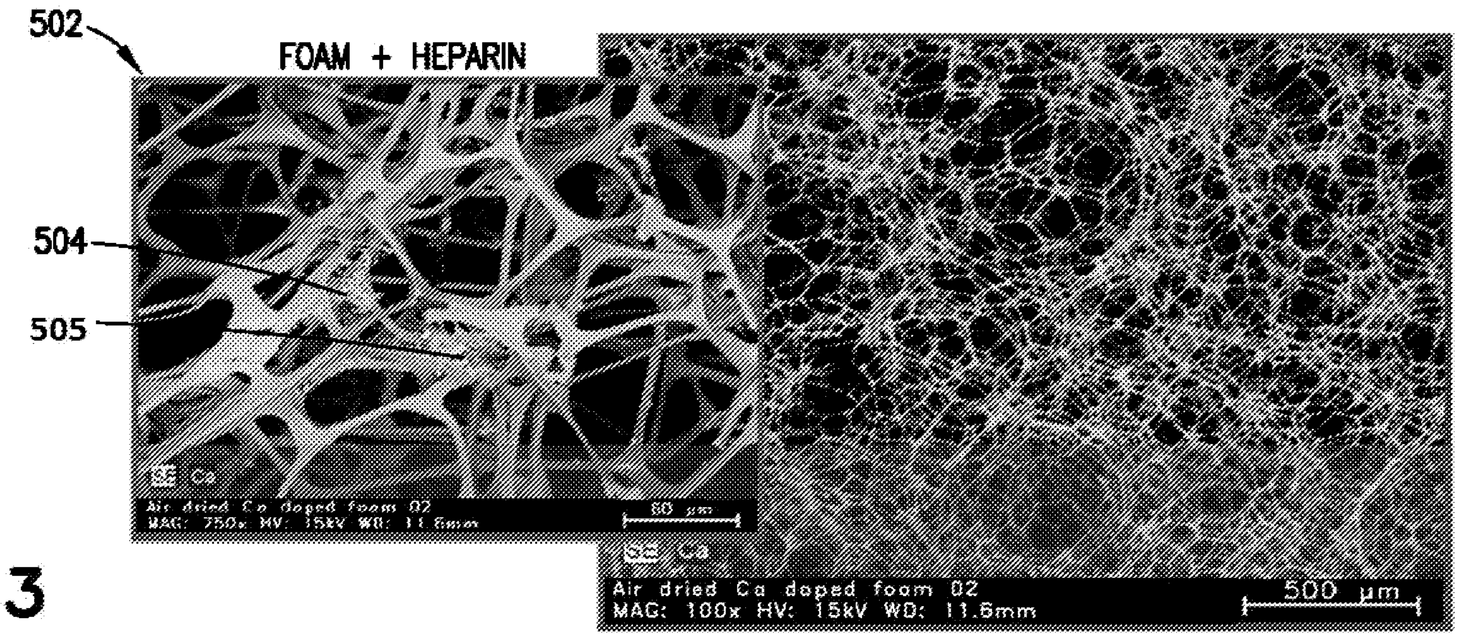
502
FOAM + HEPARIN
504
505
Air dried Ca doped foam 02
MAG: 100x HV: 15kV WD: 11.6mm
500 µm

FIG.13

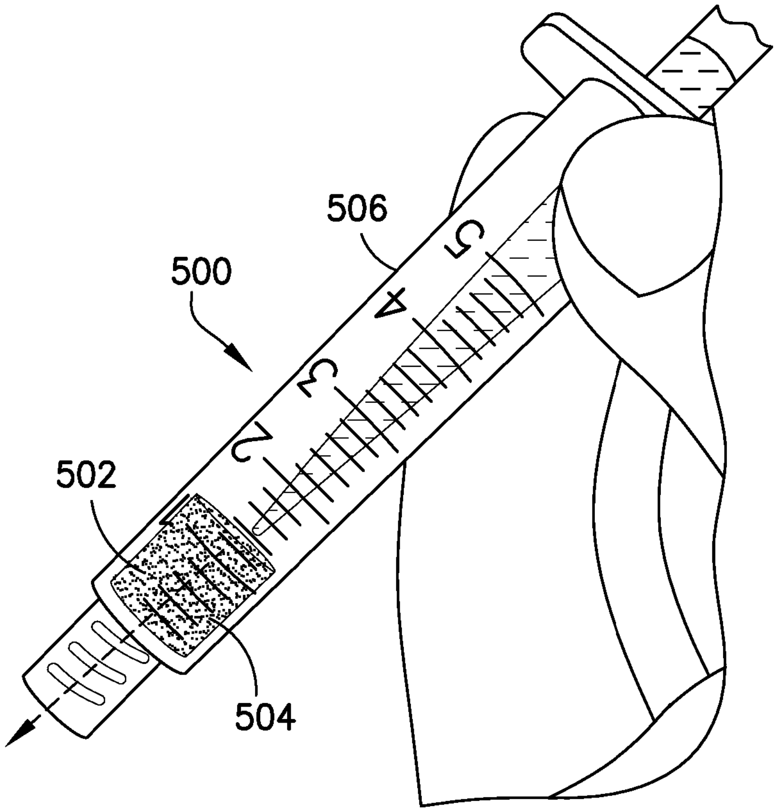

FIG.15

UNTREATED FOAM

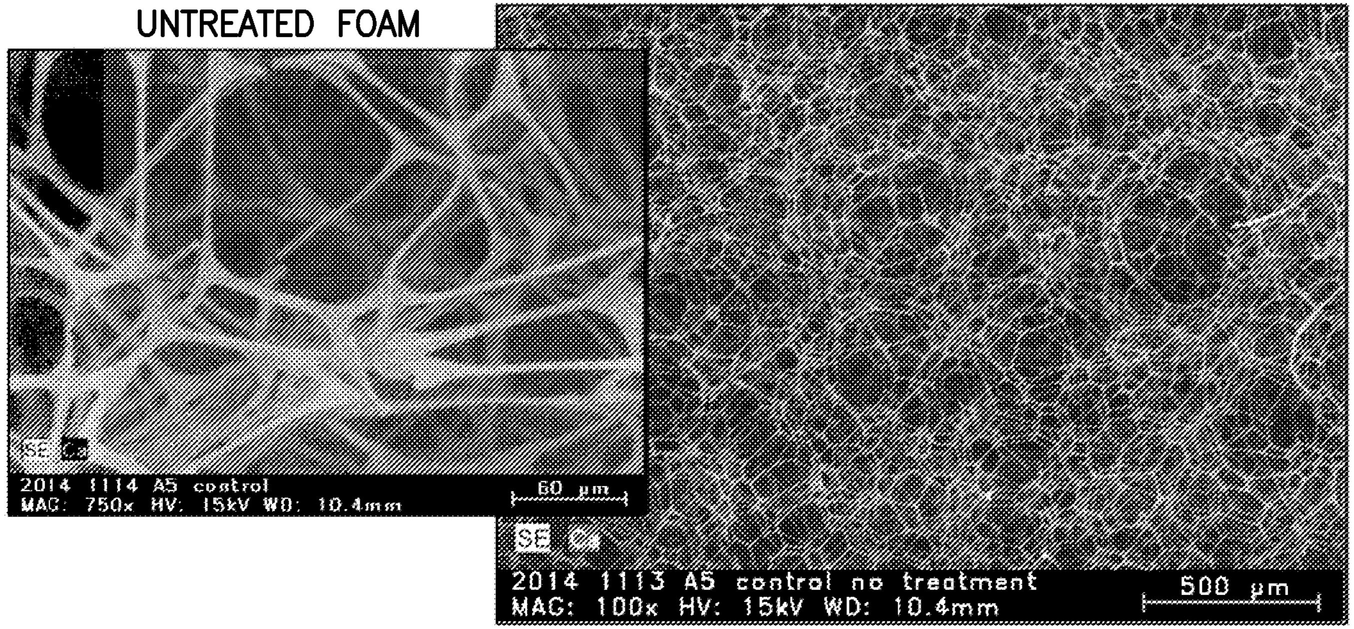

FIG.14

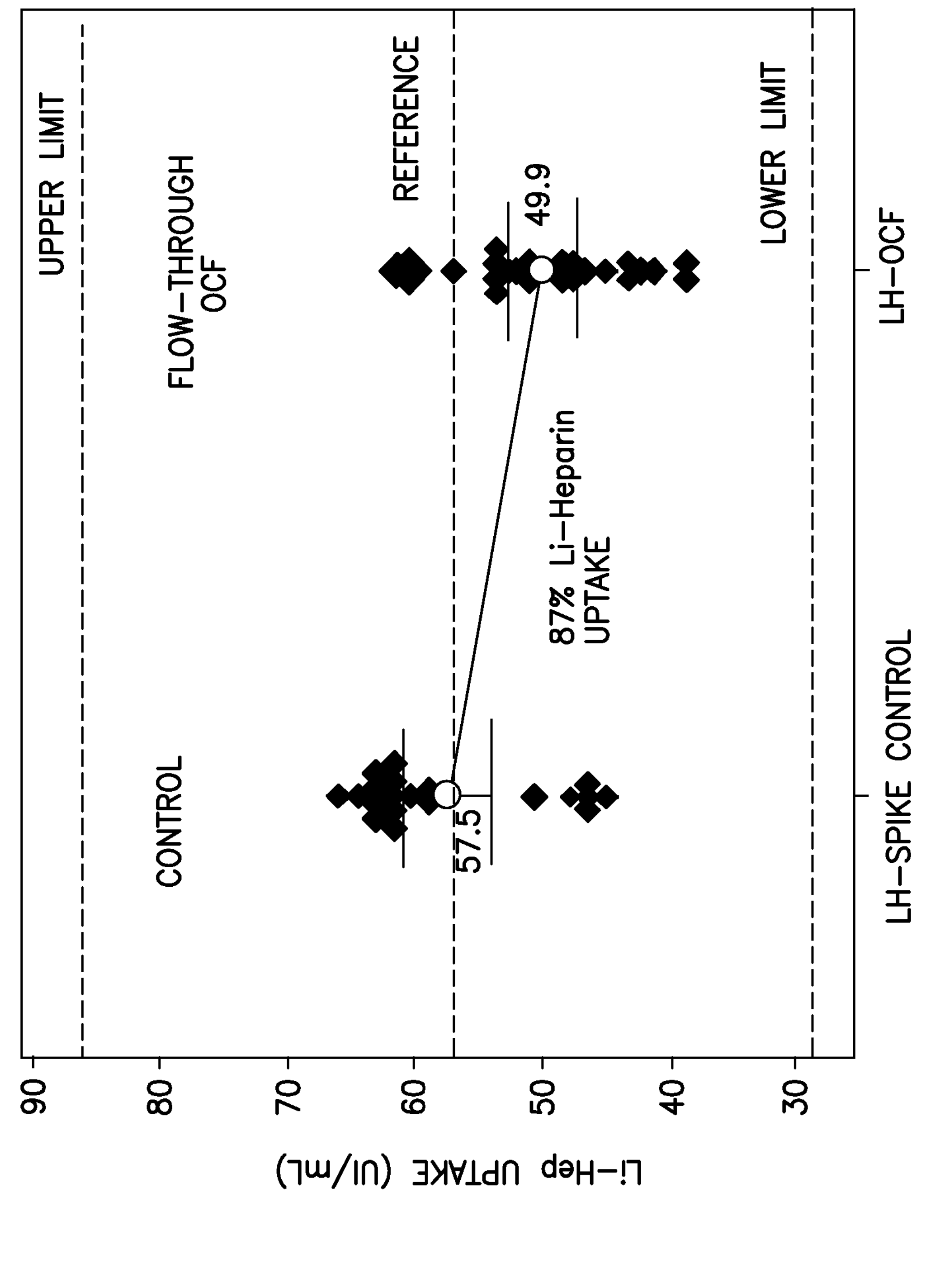
UPPER LIMIT
FLOW-THROUGH OCF
REFERENCE
LOWER LIMIT
CONTROL
57.5
49.9
87% Li-Heparin UPTAKE
LH-SPIKE CONTROL
LH-OCF
Li-Hep UPTAKE (UI/mL)
90
80
70
60
50
40
30

FIG.16

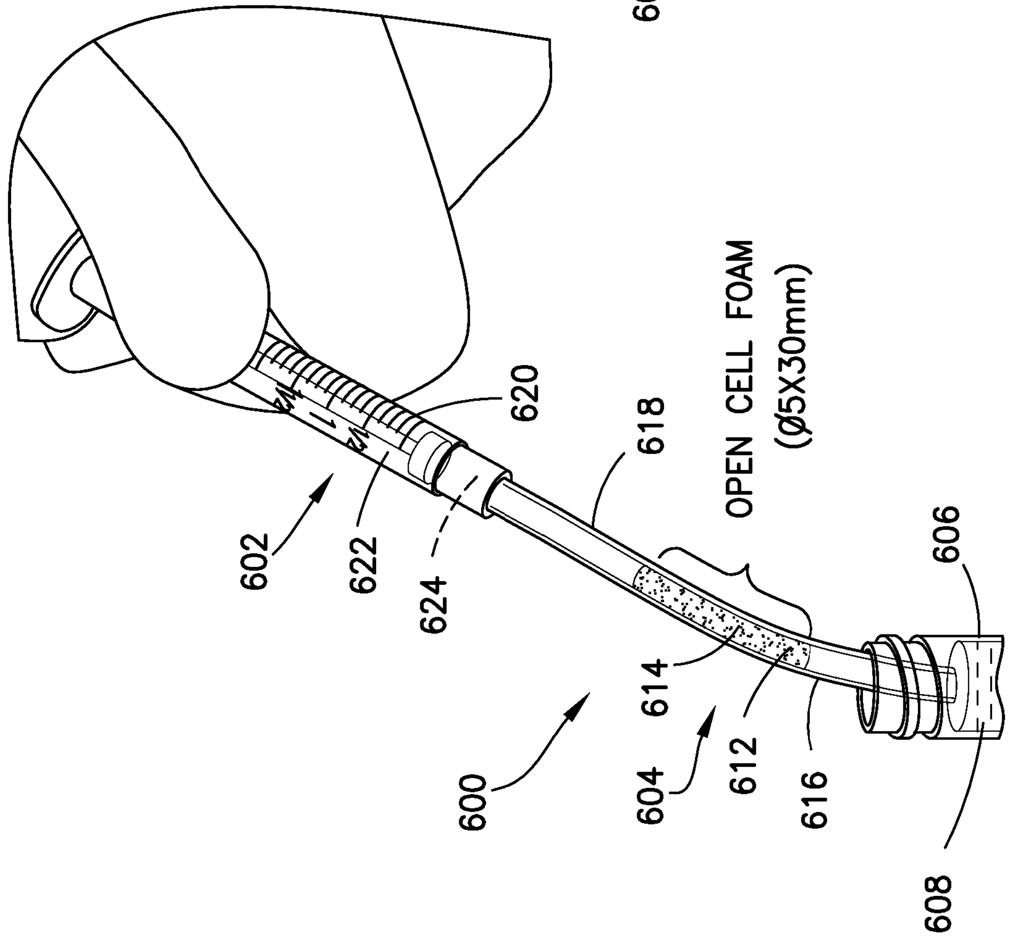
600
602
622
624
620
618
OPEN CELL FOAM
(Ø5X30mm)
604
614
612
616
606
608

FIG.17

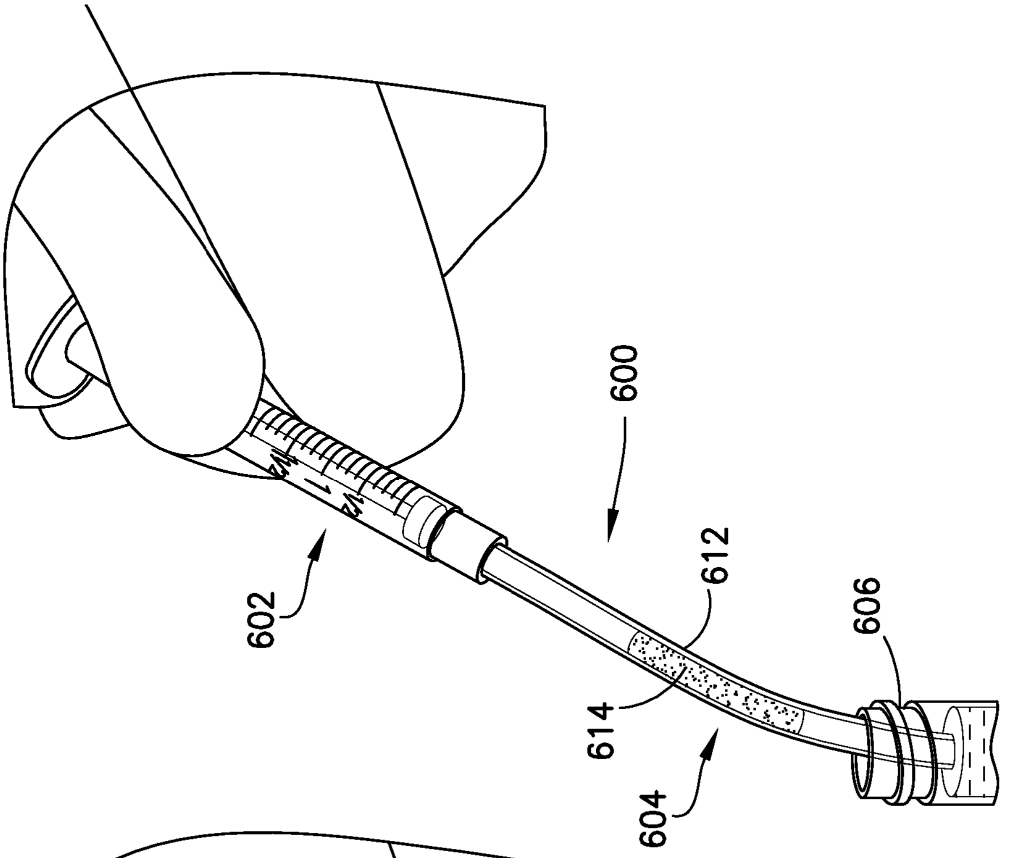
602
600
612
614
604
606

FIG.18

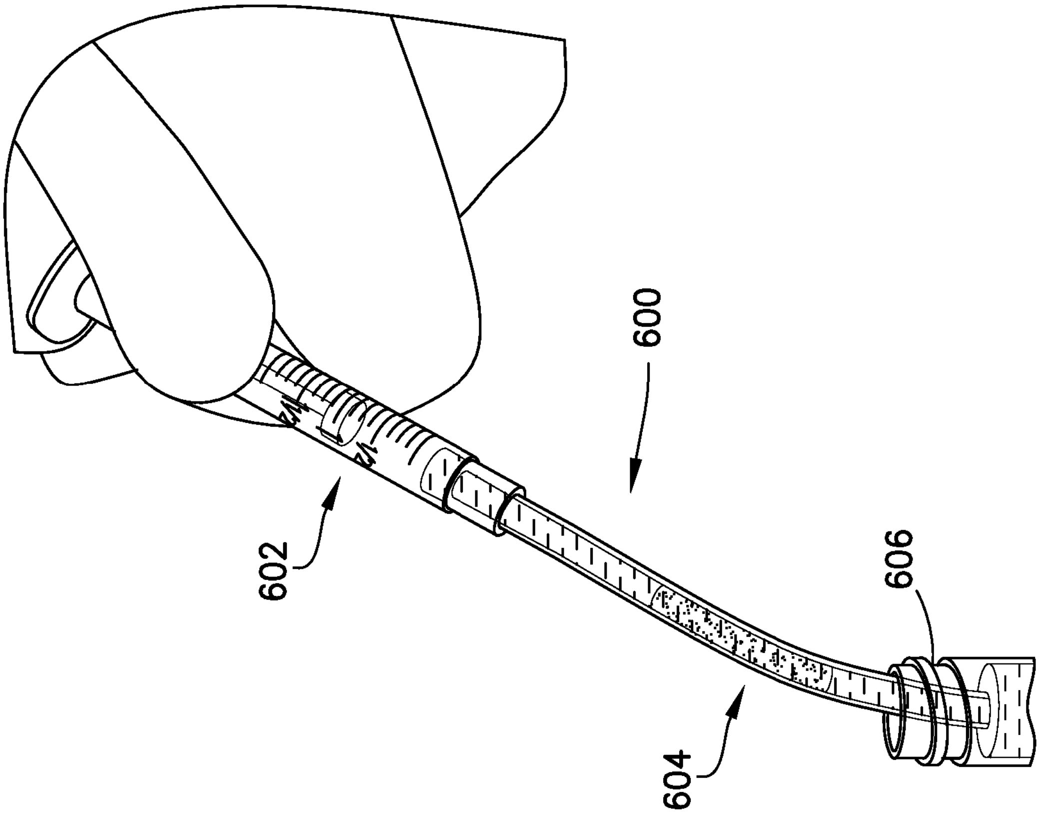

FIG.20

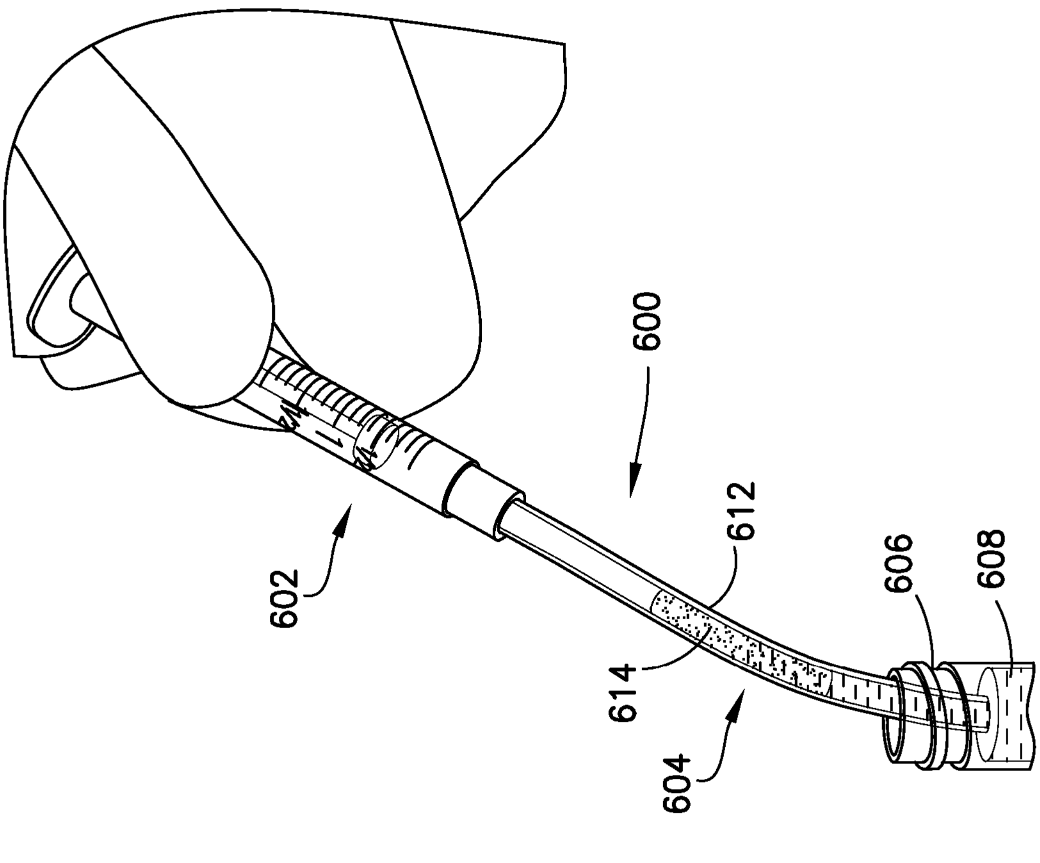

FIG.19

REFERENCES CITED IN THE DESCRIPTION

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- EP 0219053 A2 **[0003]**
- WO 2011077757 A1 **[0003]**
- WO 2009155612 A2 **[0003]**
- US 2009107903 A1 **[0003]**